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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,068	03/05/2002	H. Garrett Wada	100/08711	7955

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,068	WADA ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 14 July 2004 in which claim 1 was amended. The amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 2 April 2004 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by amendment are discussed.

Claims 1 and 4-20 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (U.S. Patent No. 5,486,335, issued 23 January 1996) in view of Juncosa et al (U.S. Patent No. 6,309,601, filed 1 May 1997).

Regarding Claim 1, Wilding et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction

and a second component of the binding reaction the second component (i.e. immobilized antibody) having a fluorescent labeled lectin "associated therewith" (Column 6, lines 25-46; Column 8, liens 10-29; Example 3: Column 11, lines 40-55 and Fig. 9-13).

Wilding et al teach the system comprising the detector but are silent regarding specific components of the detector (Abstract).

The claims have been amended to define the detectors as comprising a source of polarized light (e.g. laser as defined by the specification, page 19, lines 18-19), an optical train that directs excitation light (e.g. microscope objective, page 19, lines 21-22), means for separating the collected light (e.g. beam splitter, page 19, lines 25-26) and means for separately detecting the parallel and perpendicular components (e.g. photomultiplier tube, photo diodes or CCD, page 19,line 32-page 20, line 1).

Detectors comprising the claimed components were well known in the art at the time the claimed invention was made as taught by Juncosa et al (Column 6, lines 28-46, Column 7, lines 24-67 and Column 8, lines 5-30). Juncosa et al further teach their detector improves signal-to-noise ratio and provides high sensitivity and reliability at a relatively low cost (Column 5, lines 10-17). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the detector of Juncosa et al to the system of Wilding et al for the expected benefit of improving signal-to-noise ratio and providing high sensitivity and reliability at a relatively low cost as taught by Juncosa et al (Column 5, lines 10-17).

Regarding Claim 4, Wilding et al disclose the system wherein the second component comprises a binding fragment that is capable of binding the first component i.e. immobilized antibody (Example 3: Column 11, lines 40-55).

Regarding Claim 19, Wilding et al disclose the system wherein the cells are mammalian (Example 3: Column 11, lines 40-55).

4. Claims 1 and 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al (U.S. Patent No. 5,942,443, issued 24 August 1999) in view of Juncosa et al (U.S. Patent No. 6,309,601, filed 1 May 1997).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claim 1, Parce et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component (i.e. test compound) having a fluorescent labeled "associated therewith" (Column 7, line 40-Column 8, line 57 and Claim 7) and a detector comprising a laser and photomultiplier tube (Column 10, lines 5-13).

The claims have been amended to define the detectors as comprising a source of polarized light (e.g. laser as defined by the specification, page 19, lines 18-19), an optical train that directs excitation light (e.g. microscope objective, page 19, lines 21-22), means for separating the collected light (e.g. beam splitter, page 19, lines 25-26) and means for separately detecting the parallel and perpendicular components (e.g. photomultiplier tube, photo diodes or CCD, page 19,line 32-page 20, line 1).

Detectors comprising the claimed components were well known in the art at the time the claimed invention was made as taught by Juncosa et al (Column 6, lines 28-46, Column 7, lines 24-67 and Column 8, lines 5-30). Juncosa et al further teach their detector improves signal-to-noise ratio and provides high sensitivity and reliability at a relatively low cost

(Column 5, lines 10-17). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the detector of Juncosa et al to the system of Parse et al for the expected benefit of improving signal-to-noise ratio and providing high sensitivity and reliability at a relatively low cost as taught by Juncosa et al (Column 5, lines 10-17).

Regarding Claim 4, Parce et al disclose the system wherein the second component comprises a binding fragment that is capable of binding the first component (Column 4, line 58-67 and Column 6, line 60-Column 7, line 2).

Regarding Claims 5-20, Parce et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component (i.e. test compound) having a fluorescent labeled "associated therewith" (Column 7, line 40-Column 8, line 57 and Claim 7).

Parce et al further teach the test compound comprises peptides, proteins, nucleic acids, small organic and small inorganic molecules (Column 4, line 58-67 and Column 6, line 60-Column 7, line 2) whereby biological interactions are analysis e.g. cellular signaling, transport reactions involving cells, cellular viability and in vivo effectors (Column 4, lines 40-67). This teaching clearly suggests the instantly claimed binding partners of less than 50 amino acids (peptides), carbohydrates, lipids, cAMP (effectors), nuclei acid binding protein-nucleic acid probe (nucleic acids), translocation functionality (transport reactions) and signaling pathway (cellular signaling) but they do not specifically teach the first and second binding partners recited in Claims 5-18 and 20. However, the cellular components taught by Parce are genus of the instantly claimed species which clearly suggests the claimed species.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the genus teaching of Parce et al and to provide their system with the instantly claimed species based on the suggestion to do so of Parce et al (Abstract).

5. Claims 1, 4-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al (U.S. Patent No. 6,074,827, filed 5 February 1998) in view of Juncosa et al (U.S. Patent No. 6,309,601, filed 1 May 1997).

Regarding Claim 1, Nelson et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component having a fluorescent labeled "associated therewith" and a detector in communication with the channel (Column 10, lines 35-47; Column 20, line 58-Column 22, line 52; Column 23, line 46-Column 24; and Fig. 27). Nelson et al teach the system comprising the detector but are silent regarding specific components of the detector (Column 22, lines 46-49).

The claims have been amended to define the detectors as comprising a source of polarized light (e.g. laser as defined by the specification, page 19, lines 18-19), an optical train that directs excitation light (e.g. microscope objective, page 19, lines 21-22), means for separating the collected light (e.g. beam splitter, page 19, lines 25-26) and means for separately detecting the parallel and perpendicular components (e.g. photomultiplier tube, photo diodes or CCD, page 19,line 32-page 20, line 1).

Detectors comprising the claimed components were well known in the art at the time the claimed invention was made as taught by Juncosa et al (Column 6, lines 28-46, Column 7,

lines 24-67 and Column 8, lines 5-30). Juncosa et al further teach their detector improves signal-to-noise ratio and provides high sensitivity and reliability at a relatively low cost (Column 5, lines 10-17). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the detector of Juncosa et al to the system of Nelson et al for the expected benefit of improving signal-to-noise ratio and providing high sensitivity and reliability at a relatively low cost as taught by Juncosa et al (Column 5, lines 10-17).

Regarding Claim 4, Nelson et al disclose the system wherein the second component comprises a binding fragment that is capable of binding the first component i.e. immobilized antibody (Column 21, lines 25-49).

Regarding Claim 19, Nelson et al disclose the system wherein the cells are mammalian (Column 26, line 45-Column 27, line 9).

Regarding Claim 5-18 and 20, Nelson et al disclose a system comprising a reaction vessel and a detector. The reaction vessel having at least first and second intersecting microfluidic channels, a window providing optical access to at least one channel, and within at least the first channel, a cell suspension comprising cells having a first component of a binding reaction and a second component of the binding reaction the second component having a fluorescent labeled "associated therewith" (Column 10, lines 35-47; Column 20, line 58-Column 22, line 52; Column 23, line 46-Column 24; and Fig. 27).

Furthermore, Nelson et al teach their system comprises detection of various cells and/or cell components within the microfluidic channel e.g. nucleic acids, oligonucleotides, proteins, peptides, lipids and etc. (Column 26, line 45-Column 27, line 9) but they do not specifically teach the first and second binding partners recited in Claims 5-18 and 20. However, the cellular components taught by Nelson are genus of the instantly claimed species which clearly suggests the claimed species.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the genus teaching of Nelson et al and to provide their system with the instantly claimed species based on the suggestion to do so of Nelson et al (Abstract).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 30, 2004